

**REMARKS****Restriction Requirement**

Applicants affirm the selection of a composition comprising a combination of 5-ASA and APAZA in response to the imposed restriction requirement issued on November 30, 2009.

**Rejection of Claims and Traversal Thereof**

In the February 17, 2010 Office Action,

Claim 30 was rejected under 35 U.S.C. §112, second paragraph;

Claims 1-9, 15 and 30 were rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 7,425,578;

Claims 1, 8, 9, 15 and 30 were rejected under 35 U.S.C. §102(c) as being anticipated by Ekwuribe, et al. US Patent No. 7,425, 578; and

Claims 1-9, 15 and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ekwuribe, et al. US Patent No. 7,425, 578.

Applicants traverse these rejections and insist that the cited reference does not defeat the patentability of the presently claimed invention.

**Rejection under 35 U.S.C. §112, second paragraph**

Applicants have amended claim 30 thereby obviating this rejection. Applicants request the withdrawal of this rejection.

**Obvious-type Double Patenting Rejection**

Claims 1-9, 15 and 30 were rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 7,425,578. Applicants have included herewith a terminal disclaimer thereby obviating this rejection.

### Lack of Novelty and Inventive Step Rejections

According to the Office U.S. Patent No. 7,425,578 defeats the novelty and renders obvious the presently claimed invention. Notably, U.S. Patent No. 7,425,578 claim priority back to US Patent No. 6,583,128 with a filing date of August 29, 2001, as shown below:

(12) **United States Patent**  
**Ekwuribe et al.**

(10) **Patent No.:** **US 7,425,578 B2**  
(45) **Date of Patent:** **\*Sep. 16, 2008**

(54) **IMMUNOREGULATORY COMPOUNDS AND DERIVATIVES AND METHODS OF TREATING DISEASES THEREWITH**

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(73) Assignee: **Biocon Limited** (IN)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 24 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/470,655**

(22) Filed: **Sep. 7, 2006**

(65) **Prior Publication Data**  
US 2007/0004800 A1 Jan. 4, 2007

#### **Related U.S. Application Data**

(60) Continuation of application No. 10/967,736, filed on Oct. 18, 2004, now Pat. No. 7,151,095, which is a continuation of application No. 10/444,668, filed on May 23, 2003, now Pat. No. 6,903,082, which is a division of application No. 09/942,464, filed on Aug. 29, 2001, now Pat. No. 6,583,128.

(60) Provisional application No. 60/228,683, filed on Aug. 29, 2000.

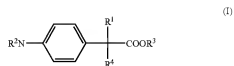
*Primary Examiner*—Kamal A. Saeed

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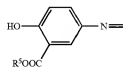
(74) *Attorney, Agent, or Firm*—Marianne Fuierer; Moore & Van Allen PLLC

(57) **ABSTRACT**

Compounds are disclosed having the structure of Formula I:



where  $R^1$ ,  $R^3$ , and  $R^4$  are independently hydrogen or  $C_1$  to  $C_4$  alkyl, and  $R^2$  is:



where  $R^5$  is selected from the group consisting of hydrogen and  $C_1$  to  $C_4$  alkyl, or

The presently claimed invention also claims priority back to US Patent No. 6,583,128 as shown below in the Filing Receipt issued for the present application.

APPLICATION NUMBER	INVENTOR	GR PATENT UNIT	FIL FEE REC'D	ATTY DOCKET NO	TOT CLAIMS	IND CLAIMS
10/594,046	09/25/2006	1614	4460	014811-673.119US	31	1

CONFIRMATION NO. 8968

## CORRECTED FILING RECEIPT

24239  
 MOORE & VAN ALLEN PLLC  
 P.O. BOX 13706  
 Research Triangle Park, NC 27709



Date Mailed: 07/24/2008

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections

## Applicant(s)

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 Rodger Liddle, Durham, NC;

**Power of Attorney:** The patent practitioners associated with Customer Number 24239

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US05/09325 03/22/2005  
 which claims benefit of 60/555,551 03/23/2004  
 This application 10/594,046  
 is a CIP of 11/144,093 06/03/2005 PAT 7,119,119  
 which is a CON of 10/444,668 05/23/2003 PAT 6,903,082  
 which is a DIV of 09/942,464 08/29/2001 PAT 6,583,128

Thus, the present invention and the US Patent No. 7,425,578 have the same effective filing date of August 29, 2001, and as such, the rejections under novelty and obviousness should be withdrawn. It should be recognized that applicants have already filed terminal disclaimers for US Patent Nos. 7,119,119, 6,903,082 and 6, 583,128 because of previously imposed obvious-type double patenting, novelty and obviousness rejections.

In conclusion, applicants and the Office have been prosecuting this application for about four year with a multiplicity of rejections and successful overcoming of such rejections. Thus, applicants believe that this application is in conditions for allowance and that all prior art has been exhausted.

**Rejoining of all species claims**

When the Office finds the present claims patentable, applicants request that all species claims be examined and found allowable.

**Petition for Extension of Time/Fees Payable**

The applicants hereby petition for a three month extension of time, extending the deadline for responding to the February 17, 2010 Office Action from May 17, 2010 to August 17, 2010. Further, applicants have included a terminal disclaimer with a fee due of \$130.00. All fees are being paid herewith by electronic transfer. In the event an additional fee is found due, the U.S. Patent and Trademark Office is hereby authorized to charge any additional amount necessary to the entry of this amendment to Deposit Account No. 13-4365 of Moore & Van Allen PLLC.

**Conclusion**

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Spivack reconsider the patentability of pending claims in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Spivack is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,

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